

REMARKS

Applicant respectfully requests reconsideration. Claims 14, 15 and 18-28 were previously pending in this application. No new matter has been added.

Renewed Request to Withdraw Finality of Rejection

Applicant respectfully requests reconsideration of the Examiner's conclusion that the finality of the Office Action was proper.

The rejection made by the Examiner in the Office Action uses the Brooke patent (US 6,328,992) as the primary reference with the Travis patent (US 6,541,510) and the Turner et al. (J Clin Pharmacol. 1981; 21:283S-291S) as secondary references. In contrast, the rejection made in the prior Office Action was made using the Travis patent as the primary reference with Turner article and Brooke patent as secondary references.

The rejection in the instant Office Action thus differs from the rejection made in the prior Office Action, as admitted by the Examiner on page 3 of the Office Action: "Because of Applicants amendments [to] the claims, the following *modified rejections* are being made." (emphasis added)

As previously argued by Applicant, the claim amendments that were made did not provoke the modification of the rejection. The amendment to claim 14 made in response to the prior Office Action was made to explicitly recite the feature of Formula 1 as defined in claim 1, which previously was recited by reference to claim 1. Therefore there was no reason for the rejection of claim 14 to have been "modified" or changed in any way based on the amendment to claim 14. Accordingly, the claim amendments did not necessitate the "modification" of the rejection, and therefore the finality of the rejection should be withdrawn.

This view is supported by MPEP 706.07, which states in the section on “Statement of Grounds” that “In making the final rejection, all outstanding grounds of rejection of record should be carefully reviewed, and any such grounds relied on in the final rejection should be reiterated.”

On pages 2-3 of the final Office Action, the Examiner did reiterate the rejection of the claims over Travis (U.S. Patent 6,541,510) in view of Turner et al. (J Clin Pharmacol. 1981; 21:283S-291S) as applied to claims 1-3, 5, 7-13 and further in view of Brooke et al. (U.S. Patent 6,328,992).

The Examiner then also rejected the claims over Brooke et al. (U.S. Patent 6,328,992) in view of Travis (U.S. Patent 6,541,510) and Turner et al. (J. Clin. Pharmacol. 1981; 21:283S-291S). This rejection clearly is in addition to the restated rejection over Travis in view of Turner et al. and further in view of Brooke et al. Accordingly, because Applicant did not have an opportunity to address this new rejection other than in response to the final rejection, the finality of the rejection of the claims over Brooke et al. in view of Travis and Turner et al. is improper.

Rejections Under 35 U.S.C. § 103

The Examiner rejected the claims under 35 U.S.C. § 103(a) as being unpatentable over (1) Travis (U.S. Patent 6,541,510) in view of Turner et al. (J Clin Pharmacol. 1981; 21:283S-291S) as applied to claims 1-3, 5, 7-13 and further in view of Brooke et al. (U.S. Patent 6,328,992), and (2) over Brooke et al. (U.S. Patent 6,328,992) in view of Travis (U.S. Patent 6,541,510) and Turner et al. (J. Clin. Pharmacol. 1981; 21:283S-291S). Applicant respectfully traverses the rejection.

The Examiner admits on page 4 of the Office Action that Brooke does not teach a compound of Formula 1 as recited in claim 1. The Examiner asserts on pages 4-5 of the Office Action that the skilled person would have been motivated to use the cannabichromene compound as taught by Travis and Turner to treat depression.

Brooke et al. does not teach the use of cannabichromene

Applicant respectfully disagrees with both the reasoning of the Examiner and the conclusions reached by the Examiner. The Brooke patent discloses methods for transdermal delivery of cannabis. The Brooke patent provides no specific disclosure of the use of cannabichromene for any given medical indication. Brooke merely provides a list of conditions for which cannabis has been used. Therefore Brooke lacks an element of the instant invention as claimed.

Moreover, the Brooke patent fails to provide an adequate written description of the use of cannabichromene in the treatment of mood disorders. The two lists provided by Brooke, for conditions possibly treatable with cannabis, and for cannabinoids present in cannabis, do not provide an adequate written description.

This concept is stated in MPEP 2163:

A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a “laundry list” disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not “reasonably lead” those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) (“If n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.”) (emphasis in original); Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) (“the specification does not clearly disclose to the skilled artisan that the inventors ... considered the ratio... to be part of their invention There is therefore no force to Purdue's argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion”).

Therefore, the skilled person in reading Brooke would not find a disclosure of using cannabinoids, particularly cannabichromene in the treatment of mood disorders.

Travis and Turner et al. do not supply the elements missing from Brooke et al.

The Travis and Turner references do not provide any teaching that cannabichromene would be useful in the treatment of mood disorders. Therefore, the Travis and Turner references do not remedy the deficiencies of Brooke.

There is no motivation to combine Brooke et al. with Travis and Turner et al.

Moreover, Applicant respectfully disagrees that the Examiner has provided a sufficient motivation to combine the Brooke, Travis and Turner references. The Examiner states that the skilled person would have been motivated to use cannabichromene compositions of Travis and Turner to treat depression “because Brooke et al. teaches that cannabichromenes show medical use in treating depression.” (Office Action at page 5) That statement is incorrect. Brooke states that the medical uses of cannabis include a variety of diseases. Brooke does not teach that cannabichromene is useful for treating any of the diseases listed at col. 1, lines 23-33. In fact the working examples in Brooke do not make use of cannabichromene. As noted above, these statements do not provide an adequate written description of the treatment of mood disorders using cannabinoids, particularly cannabichromene.

Thus Brooke does not provide motivation to the skilled person to use cannabichromene in the treatment of mood disorders. Furthermore, the skilled person would not have an expectation of success in using cannabichromene to treat mood disorders based on the disclosure of the combination of references.

Low levels of CBC in mature cannabis plants

As further evidence that the skilled person would not have an expectation of success from the cited prior art references and indeed would not be motivated to use cannabichromene, the skilled person knows that mature cannabis plants actually contain very little cannabichromene (CBC). Provided herewith in support of these statements are journal articles by Vogelmann et al. and Rowan & Fairbairn.

The paper by Vogelmann et al. (Journal of Natural Products, 51(6): 1075-1079, 1988) shows the ratios of CBC to other cannabinoids in Table 1. CBC is a minor component of the total cannabinoids in mature plants

The paper by Rowan & Fairbairn (J. Pharm. Pharmac. 29: 491-494, 1977) shows in Tables 1 and 2, and in Figure 1 that CBC levels drop precipitously in mature plants, most often to trace levels (see Table 2 in particular).

The skilled person would be aware of the relatively low CBC content of cannabis plants, compared to THC and CBD. The skilled person would therefore interpret the medicinal uses of cannabis described by Brooke to be in relation to the more major cannabinoids and would not consider CBC to be a candidate compound, less so an obvious compound, to try for any medical indication, let alone the specific one detailed by the present application.

Accordingly, the combination of the Brooke, Travis and Turner references does not provide all of the elements of the claimed invention and no motivation has been shown for making the combination. Therefore, withdrawal of the rejection of claims 14-15 and 18-28 under 35 U.S.C. § 103 is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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